In re Application of: Sergei BRAUN
Serial No.: 10/536,467
Filed: May 25, 2005
Office Action Mailing Date: February 21, 2008

Examiner: Gennadiy MESH
Group Art Unit: 1796
Attorney Docket: 29948

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 114-153 are in this Application. Claims 114-131 and 145-153 have been withdrawn from consideration as being drawn to non-elected invention. Claims 132-144 have been examined on the merits.

Claims 132-144 have been rejected under 35 U.S.C. §112, first paragraph. Claims 132-144 have been rejected under 35 U.S.C. §102. Claims 132-144 have been rejected under 35 U.S.C. §103. Claims 1-113 have been canceled in a previous response. Claims 140 and 144 have been cancelled herewith. Claim 132 has been amended herewith.

The application now comprises, after amendments, claims 114-139, 141-143, and 145-153, of which claims 114, 123, 132, and 145-153 are in independent form.

35 U.S.C. §112, first paragraph rejection

The Examiner has rejected claims 132-144 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a general method of treating protein containing substances in order to obtain promoters, followed by polycondensation of those promoters, does not reasonably provide enablement for polymers with structures claimed by Applicant in claims 132-144. The Examiner's rejection is respectfully traversed.

Specifically, the Examiner has referred to the *Wand* factors and has stated that in order to practice and use the invention, the quantity of experimentation necessary is great because claims 132-144 read on a very wide variety of compounds, there is no direction or guidance presented for making specific polymers with specific polymer structures as claimed in claims 132-144, and there is an absence of working examples concerning making and isolating specific polymers with structures as claimed in claims 132-144. The Examiner has therefore concluded that undue experimentation would be necessary to make and use the invention of claims 132-144.

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Applicant wishes to note that, as the Examiner has stated, the specification is enabling for both a method of obtaining promoters, and for polycondensation of promoters so as to form a polymer.

With regard to the Examiner's statement that the quantity of experimentation necessary is great because claims 132-144 read on a very wide variety of compounds, Applicant wishes to note that the specification of the instant application teaches how to prepare the claimed polymers, by preparing promoters from a protein containing material and condensing the promoters to form a polymer. See, for example, page 22, line 24 to page 32, line 9 of the instant application, presenting a clear, detailed, step-by-step explanation of how to prepare claimed polymers. Moreover, Examples 1-6 provide working examples concerning the making and isolating of four specific polymers.

Applicant wishes to note that the specification is enabling for obtaining any of a wide variety of promoters, as a wide variety of promoters can be obtained by treating appropriate proteinaceous materials (e.g., amino acids, peptides, polypeptides, proteins) according to the method taught in the specification. Such proteinaceous materials are commercially available and/or readily obtained using standard methods of the art.

Hence, the use of a very wide range of promoters to form polymers is enabled by the instant application, and furthermore, the use of any of a very wide range of combinations of promoters can readily be used. Therefore, as would be apparent to one of ordinary skill in the art, a very wide variety of compounds can be prepared according to the methods disclosed in the instant application.

Moreover, the condensation of the promoters is a defined and well-understood process, which results in a polymer with a predictable structure.

Furthermore, the promoters may be copolymerized with additional monomers, to thereby create additional claimed polymers.

Hence, it is well within the capability of one of ordinary skill in the art to select the appropriate starting materials, prepare the appropriate promoters and select

the appropriate condensation reaction conditions, in order to prepare any of the polymers claimed in claims 132-144.

Applicant therefore strongly believes that no great quantity of experimentation is necessary, despite the wide variety of claimed compounds, as the wide variety of claimed compounds merely reflects the wide variety of suitable starting materials (e.g., amino acids, peptides, polypeptides and proteins) available to one preparing any of the claimed polymers by the disclosed preparation and condensation of promoters (which the Examiner has stated to be enabled).

Reference is made to the following legal standards:

Patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Applicant is not required to show working examples concerning making and isolating all specific polymers claimed in claims 132-144. See, for example, MPEP §2164.02, which states that the lack of working examples will not by itself render the invention non-enabled. Furthermore, MPEP §2164.02 states that for a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient. MPEP §2164.02 states further states that proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *M.LT. v. A.B. Fortia, 11A* F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). The adequacy of a specification's description is not necessarily defeated by the need for some experimentation to determine the properties of a claimed product. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F3d 956, 965-966, 63 USPQ2d 1609, 1614 (Fed. Cir. 2002). In addition, a patent need not teach, and preferably omits, what is well known in the art. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *citing Lindemann Maschinenfabrik GMBH v. American Hoist &*

Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Thus, information that is conventional or well-known to one of ordinary skill in the art need not be disclosed by the specification.

In view of the above, it is clear that all claimed polymers can be prepared by one skilled in the art without undue experimentation.

With regard to the Examiner's statement that there is no direction or guidance presented for making specific polymers with specific polymer structures as claimed in claims 132-144, the Examiner has not specified why there is no direction or guidance. As discussed hereinabove, both a general procedure for preparing the claimed polymer and specific working examples are described in detail in the instant application. Hence, the Examiner's statement that there is **no** (Examiner's emphasis) direction or guidance is not clear.

As argued hereinabove, Applicant strongly believes that by setting forth a general procedure for preparing the claimed polymers and by showing working examples for some specific polymers, sufficient direction and guidance is provided in the specification of the instant application to allow one of ordinary skill in the art to prepare all claimed polymers without undue experimentation.

With regard to the Examiner's statement that there is an absence of working examples concerning making and isolating specific polymers with structures as claimed in claims 132-144, the Examiner has not specified why there is an absence of working examples concerning making and isolating specific claimed polymers. As discussed hereinabove, Examples 1-6 of the instant application provide working examples concerning the ***making and isolating*** of four specific claimed polymers. Hence, the Examiner's statement that there is an absence of working examples is not clear.

Moreover, as argued hereinabove, the preparation of different polymers claimed in claims 132-144 would not require conditions radically different than those of Examples 1-6 of the instant application, as a very wide range of polymers may be prepared according to the methods exemplified in Examples 1-6 simply by selecting different starting materials.

Applicant therefore strongly believes that sufficient working examples are provided in the specification of the instant application to allow one of ordinary skill in the art to prepare all claimed polymers without undue experimentation.

In view of the above arguments and amendments, Applicant strongly believes to have overcome the Examiner's rejection.

35 U.S.C. §102(b) rejection

The Examiner has rejected claims 132-144 under 35 U.S.C. §102(b) as being unpatentable over Goodman et al. (US Re. 30,170) in view of Gouesnard ("Reactivite du nitrite de sodium. V. Action sur les amino-acides, peptides et proteins", Bulletin de la Societe Chimique de France 1989 N° 1.) The Examiner's rejection is respectfully traversed. Claim 132 has been amended. Claims 140 and 144 have been canceled.

Specifically, the Examiner has stated that Goodman et al. discloses hydrolysable copolymers of natural amino acids and hydroxyacids obtained by incorporation of alpha (or beta or gamma) hydroxyacid residues in a peptide backbone, wherein amino acid and hydroxyacid are linked by an ester bond. The Examiner has further stated that radical A as Y-CO-CHR_A-O· reads on hydroxyacid residues when R_A is hydrogen and Y is OH, and that the natural amino acid residue in the general formula provided by Goodman et al. reads on radical B.

Applicant wishes to note that because the abovementioned rejection is included in a 35 U.S.C. §103 section of the Office Action, and includes language appropriate for a 35 U.S.C. §103 rejection rather than for a 35 U.S.C. §102 rejection (i.e., "unpatentable over Goodman et al. in view of Gouesnard"), it is unclear to Applicant exactly what 35 U.S.C. §102 rejection, if any, exists. Applicant therefore believes that it would be improper for the Examiner to issue a Final Office Action based on a 35 U.S.C. §102 rejection over Goodman et al. if the arguments presented herein do not satisfy the Examiner, as Applicant is prevented by the abovementioned lack of clarity from presenting herein optimal amendments and/or arguments.

Goodman et al. teaches a synthetic linear polymer, comprising specific amino acid and hydroxyacid residues, which is preferably synthesized using synthetic

derivatives of individual amino acids and hydroxyacids (see, for example, column 2, line 31 to column 3, line 19, therein).

In sharp contrast, embodiments of the present invention are of a polymer made from a modified protein-containing substrate, the polymer being preferably branched and/or cross-linked, rather than linear (see, for example, page 32, lines 10-21 of the instant application). As is discussed, for example, on page 3, line 31 to page 4, line 10, and on page 32, lines 10-27 of the instant application, linear polymers provide a narrow range of physical properties and require a high degree of monomer purity during polymerization, which raises the cost of preparation, so as to avoid premature chain termination. The inventors of the present invention have envisioned that modifying a protein-containing substrate so as to allow branching and/or cross-linking would allow the preparation of polymers with a wide range of physical properties from cheap and widely available starting materials without requiring a high degree of monomer purity.

Notwithstanding the above, and in order to expedite the prosecution, claim 132 has been amended so as to no longer recite radical A as Y-CO-CHR$_A$-O·. Accordingly, claim 132 has been further amended so as to longer recite limitations defining the variable R$_A$.

As a result of the amendment to claim 132, claims 140 and 144 have been canceled for reciting subject matter no longer encompassed by claim 132.

Hence, radical A, as recited in amended claim 132, is an amino acid residue linked via the side chain thereof to a residue represented by radical B.

The abovementioned amendment is supported, for example, on page 35, line 10, to page 42, line 1, of the instant application, wherein polymers according to amended claim 132 are described, as well as on page 32, lines 10-27, which describes the advantages of branched and/or cross-linked polymers over linear polymers. As discussed hereinabove, radical A in amended claim 132 is characterized as being linked via the side chain thereof to radical B. Hence, radical A comprises an amino acid residue which may be linked to three other moieties (specifically, X, Y and

radical B), allowing branching and cross-linking, rather than to two other moieties, as in linear polymers.

In sharp contrast, Goodman et al. teaches a linear polymer comprising a peptide backbone including hydroxyacid residues. As would be apparent to one skilled in the art, and as can further be seen in the general formula of Goodman et al., the side chains of the residues in a linear polymer are not linked to other residues in the polymer.

It is therefore Applicant's opinion that the claimed invention is not anticipated by Goodman et al. and hence, that claims 132-139 and 141-143 are allowable.

35 U.S.C. §103(a) rejections

The Examiner has indicated a rejection under 35 U.S.C. §103(a) on page 3 of the instant Office Action.

The Examiner has further stated that claims 132-144 are rejected as being unpatentable over Goodman et al. in view of Gouesnard. However, the aforementioned rejection is stated to be a 35 U.S.C. §102(b) rejection. Hence, it is unclear to Applicant which claims, if any, are rejected under 35 U.S.C. §103.

Applicant therefore believes that it would be improper for the Examiner to issue a Final Office Action based on a 35 U.S.C. §103 rejection over Goodman et al. in view of Gouesnard if the arguments presented herein do not satisfy the Examiner, as Applicant is prevented by the abovementioned lack of clarity from presenting herein optimal amendments and/or arguments.

Specifically, the Examiner has stated that Goodman et al. is silent regarding the use of specific radicals A as hydroxy amino acid residues, but that Gouesnard teaches hydroxy amino acids. The Examiner has further stated that it would be obvious to one of ordinary skill in the art to use hydroxy amino acids obtained as taught by Gouesnard instead of hydroxyacids in order to prepare hydrolysable polyesters as disclosed by Goodman et al. with reasonable expectation of success.

Applicant contends that one of ordinary skill in the art would not have been motivated to use the hydroxy amino acids taught by Gouesnard instead of

hydroxyacids in order to prepare the polymers taught by Goodman et al., for the following reasons:

Firstly, Goodman et al. specifically teaches incorporating hydroxyacid residues into a peptide backbone in order to have, at some positions of a peptide backbone, **ester bonds instead of the peptide bonds (i.e., amide bonds)** formed between amino acids (see, for example, column 1, lines 13-18, of Goodman et al.).

As would be apparent to one skilled in the art, a hydroxy amino acid is liable to form an amide bond (via the amino group thereof) instead of the ester bond desired according to the teachings of Goodman et al. The teachings of Goodman et al. can therefore be achieved with a hydroxy amino acid only if the amino group in the hydroxy amino acid **does not** react to form an amide bond, and the hydroxy group therein **does** react to form an ester bond. Goodman et al. does not even remotely suggest how such a selective reactivity can be achieved.

Hence, the use of a hydroxy amino acid instead of the hydroxyacids taught in Goodman et al. would create, for no apparent reason, the technical difficulty of having to prevent amide bond formation, in order to facilitate the desired ester bond formation.

Applicant therefore believes that the modification of the hydroxyacids taught by Goodman et al. so as to include an amino group would render the hydroxyacids unsatisfactory for the purpose intended by Goodman et al.

As discussed in MPEP §2143.01, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Secondly, Goodman et al. teaches that the object of the invention taught therein is to provide a polymeric material which is more hydrolyzable than polypeptides such as silk and collagen, and therefore more suitable for use in absorbable sutures (see, for example, column 1, lines 25-58, therein). In order to achieve this object, Goodman et al. teaches a linear polymer having hydrolyzable ester bonds (see, for example, column 3, lines 24-37, therein).

As is well known in the art, the introduction of branching and/or cross-linking of polymer molecules would be expected to make the polymer less hydrolyzable.

In addition, it would be apparent to one skilled in the art that if the hydroxy acids taught in Goodman et al. were substituted with an amino group, the amino group would be capable of reacting with an amino acid and/or hydroxyacid so as to form a branched or cross-linked polymer.

Hence, it would be contrary to the stated object of the invention of Goodman et al. to modify either the amino acid or hydroxy acid residues taught by Goodman et al. so as to include a reactive functional group (e.g., an amino group) capable of inducing branching and/or cross-linking of the polymer taught therein.

Indeed, Goodman et al. specifically defines the side groups of the polymer taught therein (i.e., R, R_1, R_2 and R_3) as being alkyl, aryl, aralkyl or alkaryl (see for example, column 1, line 60, to column 2, line 12, therein). As would be apparent to one skilled in the art, the side groups specified by Goodman et al. are all relatively non-reactive and would not induce branching or cross-linking of the polymer, thereby preserving the linear structure taught therein. By specifically excluding common amino acids which comprise more reactive functional groups (e.g., hydroxy, amino, carboxy), Goodman et al. teaches away from using such amino acids.

Applicant therefore believes that the modification of the polymer taught by Goodman et al. so as to comprise the hydroxy amino acid residues taught by Gouesnard instead of hydroxyacid residues would render the polymer unsatisfactory for the purpose intended by Goodman et al.

As discussed in MPEP §2143.01, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

Thirdly, Goodman et al. teaches a synthetic polymer comprising specific amino acid and hydroxyacid residues, which is preferably synthesized using synthetic derivatives of individual amino acids and hydroxyacids (see, for example, column 2, line 31 to column 3, line 19, therein). As described hereinabove, Goodman et al. teaches away from using many common natural amino acids.

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One skilled in the art would therefore not be motivated by Goodman et al. to use modified natural amino acids instead of the specific hydroxyacids taught and defined therein.

In sharp contrast, embodiments of the present invention are of a polymer made from a modified protein-containing substrate. As discussed in the instant application (see, for example, page 25, lines 8-14, therein) and exemplified in the Examples therein (see, for example, Example 1 on pages 44-45 therein), natural protein sources are suitable for use as the protein-containing substrate from which the polymer is made. As further discussed in the instant application, natural protein sources are advantageous in that they are commonly inexpensive and easily acquired, and in that they allow the production of a wide variety of polymers (see, for example, page 3, line 31, to page 4, line 7, therein).

Thus, the modification of natural amino acids is an advantageous feature of embodiments of the present invention, but would serve no point or purpose in the synthetic polymer taught by Goodman et al.

In view of the abovementioned reasons, Applicant strongly believes that one of ordinary skill in the art would not have been motivated to modify the polymer taught by Goodman et al. by replacing the hydroxyacids taught therein with the hydroxy amino acids taught by Gouesnard.

Applicant therefore believes that claims 132-139 and 141-143 are not rendered obvious by Goodman et al. in view of Gouesnard, and are therefore allowable.

In view of the above amendments and remarks it is respectfully submitted that claims 132-139 and 141-143 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

Date: June 23, 2008

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Enclosure:

- Petition for Extension of Time(1 Month)